



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

APR 30 2002

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In re application of:

CHIOCCA *et al.*

Appl. No. 10/035,216

Filed: January 4, 2002

For: **Viral Delivery System for  
Infectious Transfer of Large  
Genomic DNA Inserts**

Confirmation No. 3452

Art Unit: 1633

Examiner: *To Be Assigned*

Atty. Docket: 0609.5050005/JAG/KRM/FRC

### Information Disclosure Statement

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language document AO1, cited on Form PTO 1449:

Document AO1, International Patent Appl. No. WO 99/06582 is in the German language. An English language abstract of document AO1 can be found on the front page of the application.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

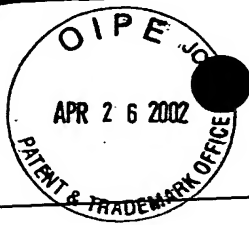
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Date: APR. 26, 2002

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## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.5050005/JAG/KRM/FRC

TECH CENTER 1600/2900

APPLICANT  
Chiocca et al.FILING DATE  
01/04/2002GROUP  
1633

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA1	5,275,942	01/04/1994	Vos	435	172.3	12/16/1991
	AB1	5,601,818	02/11/1997	Freeman et al.	424	93.21	12/08/1994
	AC1	5,631,236	05/20/1997	Woo et al.	514	44	08/26/1993
	AD1	5,670,488	09/23/1997	Gregory et al.	514	44	10/13/1993
	AE1	5,688,773	11/18/1997	Chiocca et al.	514	44	10/28/1994
	AF1	5,691,177	11/25/1997	Guber et al.	435	172.3	06/05/1995
	AG1	5,695,967	12/09/1997	Van Bokkelen et al.	435	91.1	06/07/1995
	AH1	5,741,486	04/21/1998	Pathak et al.	424	93.21	06/06/1995
	AI1	5,756,283	05/26/1998	Wilson et al.	435	5	06/05/1995
	AJ1	5,763,217	06/09/1998	Cynader et al.	435	69.1	10/11/1995
	AK1	5,763,242	06/09/1998	Zhang et al.	435	172.3	02/08/1995

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
	AL1	WO 93/12233	06/24/1993	WIPO			Yes No
	AM1	WO 95/06486	03/09/1995	WIPO			Yes No
	AN1	WO 97/05263	02/13/1997	WIPO			Yes No
	AO1	WO 99/06582	02/11/1999	WIPO			Yes No X
	AP1	WO 00/12693	03/09/2000	WIPO			Yes No

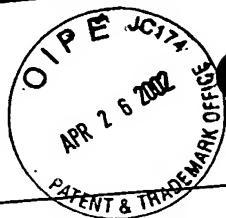
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Aboody-Guterman, K.S., et al., "Green fluorescent protein as a reporter for retrovirus and helper virus-free HSV-1 amplicon vector-mediated gene transfer into neural cells in culture and in vivo," Neuroreport 8:3801-3808, Rapid Science Publishers (1997).
AS	1	Altshuler, D., et al., "Guilt by association," Nat. Genet. 26:135-137, Nature Publishing Co. (October 2000).
AT	1	Antoch, M.P., et al., "Functional Identification of the Mouse Circadian Clock Gene by Transgenic BAC Rescue," Cell 89:655-667, Cell Press (1997).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA2	5,851,808	12/22/1998	Elledge et al.	435	172.3	02/28/1997
	AB2	5,869,294	02/09/1999	Harrington et al.	435	91.1	09/20/1996
	AC2	5,888,732	03/30/1999	Hartley et al.	435	6	06/07/1996
	AD2	6,143,557	11/07/2000	Hartley et al.	435	320.1	01/20/1999
	AE2	6,143,566	11/07/2000	Heintz et al.	435	463	06/23/1997
	AF2	6,171,861	01/09/2001	Hartley et al.	435	455	01/12/1998
	AG2	6,270,969	08/07/2001	Hartley et al.	435	6	01/20/1999
	AH2	6,277,608	08/21/2001	Hartley et al.	435	91.4	04/22/1999
	AI2	6,277,621	08/21/2001	Horsburgh et al.	435	235.1	02/26/1998
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FOREIGN PATENT DOCUMENTS

TRANSLATION

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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	WO 00/28016	05/18/2000	WIPO		Yes No
	AM2	WO 00/29000	05/25/2000	WIPO		Yes No
	AN2	WO 00/34497	06/15/2000	WIPO		Yes No
	AO2	WO 00/52027	09/08/2000	WIPO		Yes No
	AP2	WO 01/31039	05/03/2001	WIPO		Yes No

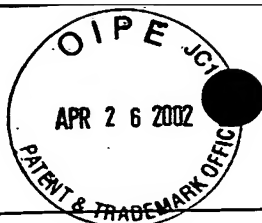
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Banerjee, S., et al., "Therapeutic gene delivery in human B-lymphoblastoid cells by engineered non-transforming infectious Epstein-Barr virus," Nat. Med. 1:1303-1308, Nature Publishing Co. (1995).
AS	2	Bilbao, G., et al., "Adenoviral/retroviral vector chimeras: a novel strategy to achieve high-efficiency stable transduction in vivo," FASEB J. 11:624-634, Federation of American Societies for Experimental Biology (1997).
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>	ATTY. DOCKET NO. 0609.5050005/JAG/KRM/FRC	APPLICATION NO. 10/035,216
	APPLICANT Chiocca et al.	
	FILING DATE 01/04/2002	GROUP 1633

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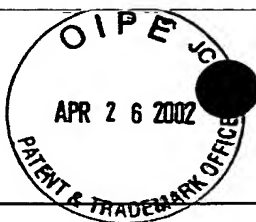
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Bobo, R.H., et al., "Convection-enhanced delivery of macromolecules in the brain," <i>Proc. Natl. Acad. Sci.</i> 91:2076-2080, National Academy of Sciences (1994).
AS	3	Breakfield, X.O., et al., "4. Herpes Simplex Virus Vectors for Tumor Therapy," in: <i>The Internet Book of Gene Therapy: Cancer Therapeutics</i> , Sobol, R.E. and Scanlon, K.J., eds., Appleton and Lange, Stamford, Connecticut, pp. 41-56 (1995).
AT	3	Brune, W., et al., "Forward with BACs new tools for herpesvirus genomics," <i>Trends Genet.</i> 16:254-259, Elsevier Trends Journals (June 2000).

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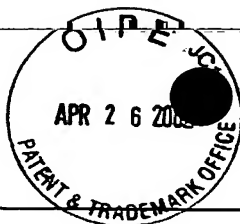
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	AR	4	Caskey, C.T. and Kruh, G.D., "The HPRT Locus," Cell 16:1-9, Massachusetts Institute of Technology (1979).
	AS	4	Chase, M., et al., "An oncolytic viral mutant that delivers the CYP2B1 transgene and augments cyclophosphamide chemotherapy," Nat. Biotechnol. 16:444-448, Nature Publishing Co. (1998).
	AT	4	Compton, S.H., et al., "Stable integration of large (> 100kb) PAC constructs in HaCaT keratinocytes using an integrin-targeting peptide delivery system," Gene Ther. 7:1600-1605, Macmillan Publishers Ltd. (September 2000).

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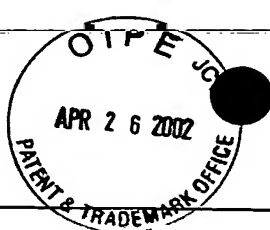
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Cunningham, C. and Davidson, A.J., "A Cosmid-Based System for Constructing Mutants of Herpes Simplex Virus Type 1," <i>Virology</i> 197:116-124, Academic Press, Inc. (1993).
	AS	<u>5</u>	Davidson, B.L., et al., "Identification of 17 Independent Mutations Responsible for Human Hypoxanthine-Guanine Phosphoribosyltransferase (HPRT) Deficiency," <i>Am. J. Hum. Genet.</i> 48:951-958, University of Chicago Press (1991).
	AT	<u>5</u>	Davidson, B.L., et al., "A model system for <i>in vivo</i> gene transfer into the central nervous system using an adenoviral vector," <i>Nat. Genet.</i> 3:219-223, Nature Publishing Co. (1993).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Delecluse, H.-J., et al., "Propagation and recovery of intact, infectious Epstein-Barr virus from prokaryotic to human cells," <i>Proc. Natl. Acad. Sci. USA</i> 95:8245-8250, National Academy of Sciences (1998).
	AS	6	Dornburg, R., "Reticuloendotheliosis viruses and derived vectors," <i>Gene. Ther.</i> 2:301-310, Stockton Press (1995).
	AT	6	During, M.J., et al., "Long-Term Behavioral Recovery in Parkinsonian Rats by an HSV Vector Expressing Tyrosine Hydroxylase," <i>Science</i> 266:1399-1403, American Association for the Advancement of Science (1994).

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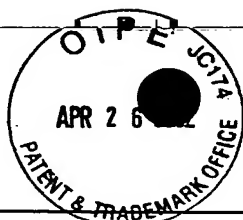
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Evans, G.A., et al., "High efficiency vectors for cosmid microcloning and genomic analysis," <i>Gene</i> 79:9-20, Elsevier Science B.V. (1989).
	AS	7	Feng, M., et al., "Stable in vivo gene transduction via a novel adenoviral/retroviral chimeric vector," <i>Nat. Biotechnol.</i> 15:866-870, Nature Publishing Co. (1997).
	AT	7	Flotte, T.R. and Carter, B.J., "Adeno-associated virus vectors for gene therapy," <i>Gene Ther.</i> 2:357-362, Stockton Press (1995).

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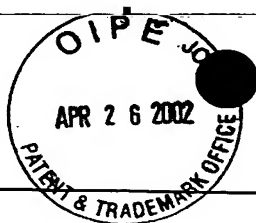
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Fraefel, C., et al., "Helper Virus-Free Transfer of Herpes Simplex Virus Type 1 Plasmid Vectors into Neural Cells," <i>J. Virol.</i> 70:7190-7197, American Society for Microbiology (1996).
	AS	8	Fraefel, C., et al., "Gene Transfer into Hepatocytes Mediated by Helper Virus-Free HSV/AAV Hybrid Vectors," <i>Mol. Med.</i> 3:813-825, Springer (1997).
	AT	8	Fraefel, C., et al., "4. HSV-1 Amplicon," in: <i>Gene Therapy for Neurological Disorders and Brain Tumors</i> , Chiocca, E.A. and Breakefield, X.O., eds., Humana Press, Totowa, New Jersey, pp. 63-82 (1998).

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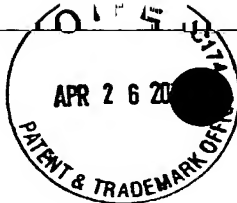
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Gardella, T., et al., "Detection of Circular and Linear Herpesvirus DNA Molecules in Mammalian Cells by Gel Electrophoresis," <i>J. Virol.</i> 50:248-254, American Society for Microbiology (1984).
	AS	9	Geller, A.I. and Breakefield, X.O., "A Defective HSV-1 Vector Expresses <i>Escherichia coli</i> $\beta$ -Galactosidase in Cultured Peripheral Neurons," <i>Science</i> 241:1667-1669, American Association for the Advancement of Science (1988).
	AT	9	Geller, A.I., et al., "An efficient deletion mutant packaging system for defective herpes simplex virus vectors: Potential applications to human gene therapy and neuronal physiology," <i>Proc. Natl. Acad. Sci. USA</i> 87:8950-8954, National Academy of Sciences (1990).

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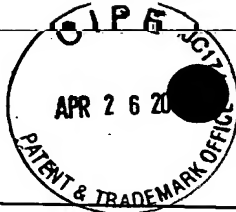
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>10</u>	Glorioso, J.C., et al., "Chapter 1. Herpes Simplex Virus as a Gene-Delivery Vector for the Central Nervous System," in: <i>Viral Vectors: Gene Therapy and Neuroscience Applications</i> , Kaplitt, M.G. and Loewy, A.D., eds. Academic Press, Inc., New York, New York, pp. 1-23, (1995).
	AS	<u>10</u>	Hammerschmidt, W. and Sugden, B., "Identification and Characterization of oriLyt, a Lytic Origin of DNA Replication of Epstein-Barr Virus," <i>Cell</i> 55:427-433, Cell Press (1988).
	AT	<u>10</u>	Hammerschmidt, W. and Sugden, B., "Genetic analysis of immortalizing functions of Epstein-Barr virus in human B lymphocytes" <i>Nature</i> 340:393-397, Macmillan Journals Ltd. (1989).

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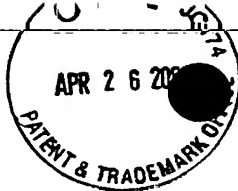
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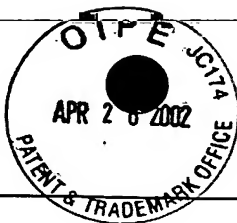
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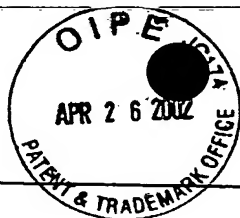
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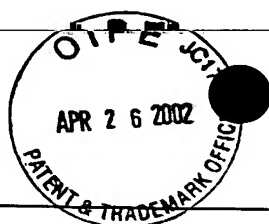
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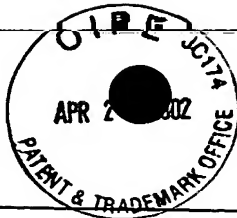
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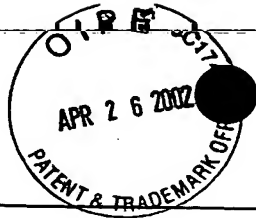
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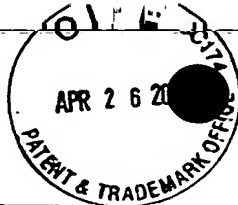
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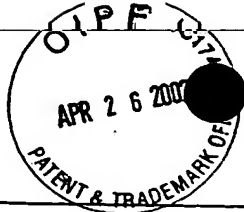
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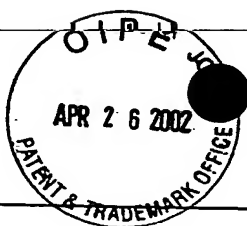
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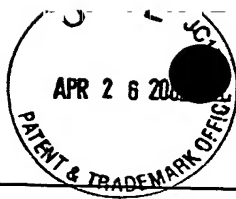
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FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0609.5050005/JAG/KRM/FRCAPPLICATION NO.  
10/035,216APPLICANT  
Chiocca et al.FILING DATE  
01/04/2002GROUP  
1633

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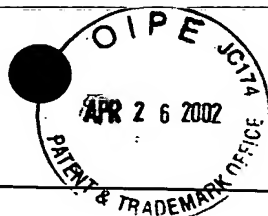
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	AR	<u>24</u>	Shizuya, H., et al., "Cloning and stable maintenance of 300-kilobase-pair fragments of human DNA in <i>Escherichia coli</i> using an F-factor-based vector," <i>Proc. Natl. Acad. Sci. USA</i> 89:8794-8797, National Academy of Sciences (1992).
	AS	<u>24</u>	Simon, M.I., "Dysfunctional genomics: BACs to the rescue," <i>Nat. Biotechnol.</i> 15:839, Nature Publishing Co. (1997).
	AT	<u>24</u>	Smith, I.L., et al., "Evidence That The Herpes Simplex Virus Immediate Early Protein ICP27 Acts Post-Transcriptionally during Infection to Regulate Gene Expression," <i>Virology</i> 186:74-86, Academic Press, Inc. (1992).

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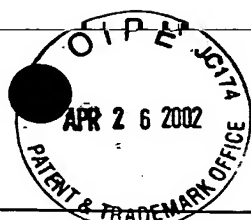
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>25</u>	Smith, G.A. and Enquist, L.W., "A self-recombining bacterial artificial chromosome and its application for analysis of herpesvirus pathogenesis," <i>Proc. Natl. Acad. Sci. USA</i> 97:4873-4878, National Academy of Sciences (April 2000).
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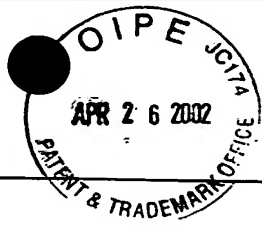
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	26	Sternberg, N., "Bacteriophage P1 cloning system for the isolation, amplification, and recovery of DNA fragments as large as 100 kilobase pairs," <i>Proc. Natl. Acad. Sci. USA</i> 87:103-107, National Academy of Sciences (1990).
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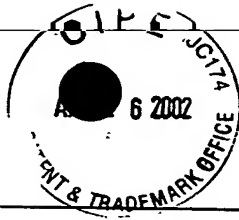
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AR	27	Vos, J.-M.H., "The simplicity of complex MACs," <i>Nat. Biotechnol.</i> 15:1257-1259, Nature Publishing Co. (1997).
AS	27	Vos, J.-M.H., "Mammalian artificial chromosomes as tools for gene therapy," <i>Curr. Opin. Genet. Dev.</i> 8:351-359, Current Biology Ltd. (1998).
AT	27	Wade-Martins, R., et al., "Long-term stability of large insert genomic DNA episomal shuttle vectors in human cells," <i>Nucl. Acids Res.</i> 27:1674-1682, Oxford University Press (1999).

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	AR	<u>28</u>	Wade-Martins, R., et al., "Stable correction of a genetic deficiency in human cells by an episome carrying a 115 kb genomic transgene," <i>Nat. Biotechnol.</i> 18:1311-1314, Nature Publishing Co. (December 2000).
	AS	<u>28</u>	Wade-Martins, R., et al., "An infectious transfer and expression system for genomic DNA loci in human and mouse cells," <i>Nat. Biotechnol.</i> 19:1067-1070, Nature Publishing Co. (November 2001).
	AT	<u>28</u>	Wang, M., et al., "Human Artificial Episomal Chromosomes (HAECs) for Building Large Genomic Libraries," in: <i>Human Genome Program, U.S. Department of Energy, Human Genome Program Report, Part 2, 1996 Research Abstracts, Human Genome Management Information System, Oak Ridge National Laboratory, Oak Ridge, Tennessee, p. 30 (1997).</i>

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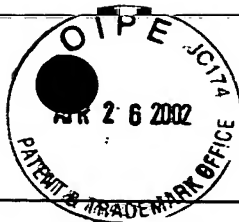
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	AR	29	Wang, S. and Vos, J.-M., "A Hybrid Herpesvirus Infectious Vector Based on Epstein-Barr Virus and Herpes Simplex Virus Type 1 for Gene Transfer into Human Cells In Vitro and In Vivo," <i>J. Virol.</i> 70:8422-8430, American Society for Microbiology (1996).
	AS	29	Wang, S., et al., "A novel herpesvirus amplicon system for in vivo gene delivery," <i>Gene Ther.</i> 4:1132-1141, Stockton Press (1997).
	AT	29	Wang, X., et al., "Fifty-One Kilobase HSV-1 Plasmid Vector Can Be Packaged Using a Helper Virus-Free System and Supports Expression in the Rat Brain," <i>BioTechniques</i> 28:102-107, Eaton Publishing Co. (January 2000).

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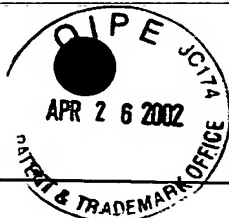
	AR	<u>30</u>	Watson, J.D., et al., "Working toward Human Gene Therapy," in: <i>Recombinant DNA</i> , 2nd Ed. Chapter 28, Watson, J.D., et al., eds. Scientific American Books, New York, New York, pp. 567-581 (1992).
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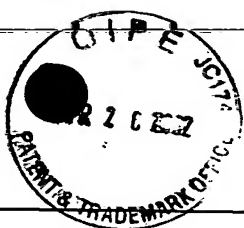
## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>31</u>	Wohlgemuth, J.G., et al., "Long-term gene expression from autonomously replicating vectors in mammalian cells," <i>Gene Ther.</i> 3:503-512, Stockton Press (1996).
	AS	<u>31</u>	Wolf, H., et al., "Epstein-Barr Virus and Its Interaction with the Host," <i>Intervirology</i> 35:26-39, S. Karger (1993).
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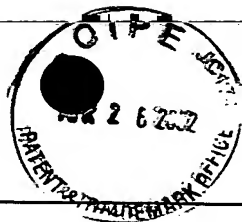
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	AR	32	Yang, X.W., et al., "Homologous recombination based modification in <i>Escherichia coli</i> and germline transmission in transgenic mice of a bacterial artificial chromosome," <i>Nat. Biotechnol.</i> 15:859-865, Nature Publishing Co. (1997).
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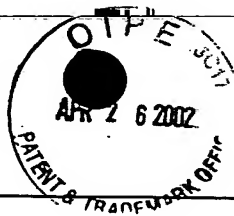
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